

Docket No.: 13796-00002-US
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
LJ, Guoqiao et al.

Application No.: 10/587,277

Confirmation No.:4870

Filed: July 25, 2006

Art Unit: No.:1616

RCE filed September 8, 2009

For: COMPOUND ARTEMISININ

Examiner: Arnold, Ernst V

INVENTORS RESUMES TO APPEND SUPPLEMENTAL DECLARATION

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

On October 29, 2009 we submitted an Amendment and Supplemental Declaration in Response to an Office Action dated May 8, 2009 and to be submitted to a RCE filed September 8, 2009. The inventor's resumes that are referenced in the Supplemental Declaration were inadvertently omitted.

Please append these resumes to the Supplemental Declaration and consider them as an integral part of that document.

Accordingly, applicants believe no fee is due with this submission. However, if any fee is due for any reason, the USPTO is hereby authorized and requested to charge our Deposit Account No. 03-2775, under Order No. 13796-00002-US from which the undersigned is authorized to draw.

Respectfully submitted,

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Resume

Name: LI Guoqiao

Education background:

period	College or University	Speciality	Degree
Sep.1951-Jun.1955	Guangdong Academy of Traditional Chinese Medicine	traditional Chinese medicine	
Aug.1955-Aug.1956	South China College of Medicine (i.e., Zhongshan College of Medicine)	physiology	advanced studies
Nov. 1984-Feb. 1985	College of Tropical Medicine, Thailand Mahidol University	Tropical diseases	advanced studies

Work Experience:

Period	Employer	Duty	professional title
Aug.1955.-Aug.1956	Guangdong Jinxiu School of Traditional Chinese Medicine		teacher
Sep.1956-Jan.1960	Teaching and Research Section of Physiology, Guangzhou College of Traditional Chinese Medicine		tutor
Jan.1960-Jun.1967	Teaching and Research Section of Acupuncture, Guangzhou College of Traditional Chinese Medicine	secretary	teacher
Jul.1967-Jun.1983	Teaching and Research Section of Malaria, Guangzhou College of Traditional Chinese Medicine	Director	lecturer
Oct.1979-Sep.1997	Guangzhou University of Traditional Chinese Medicine	vice-president	
Jul.1983-Dec.1986	Teaching and Research Section of Malaria, Guangzhou College of Traditional Chinese Medicine		associate professor
Dec.1986-Sep.1997	Institute of Tropical Medicine, Guangzhou University of Traditional Chinese Medicine	Director	professor
Dec.1986-now	College of Tropical Medicine,		professor

	Guangzhou University of Traditional Chinese Medicine		
Aug. 2006-now	Search Center of Artemisia, Guangzhou University of Traditional Chinese Medicine	director	professor
Jan. 2006-now	Mainly focus on anti-malaria work in Africa		

Part-time Jobs (in academic organizations at home and abroad):

Period	Work unity	Duty
Mar.1981-Mar.1987	Malaria Special Panel of Medical Science Association of Ministry of Health	committeeman
May.1988-Apr.1993	The 3 rd Science Committee of Chinese Medical Sciences	specially invited committeeman
Jan.1988-Dec.1993	The 2 nd and 3 rd Drug Evaluation Committee of Ministry of Health	committeeman
Jun.1989- now	Chinese Journal of Infectious Diseases	member of an editorial board
Aug.1993-Aug.2006	Tropical Diseases and Parasitology Panel of Chinese Medical Association	member of the standing committee
1996, 2000	WHO Western Pacific Region	temporary adviser of malaria
1998.10-now	Society of Tropical Medicine of Guangdong Province	deputy director

LI Guoqiao was born in Nanhai county of Guangdong Province in 1936 and graduated from Guangdong Academy of Traditional Chinese Medicine in 1955. He is a chief professor and a doctoral supervisor in Guangzhou University of Chinese Medicine, a member of the standing committee in Tropical Diseases and Parasitology Affiliate of Chinese Medical Association, and a member of an editorial board of Chinese Journal of Infectious Diseases. He was an vice-president in Guangzhou University of Chinese Medicine, a superintendent in College of Tropical Medicine of Guangzhou University of Chinese Medicine, a committeeman of Malaria Special Panel of Medical Science Association of Ministry of Health, specially invited committeeman of the 3rd Science Committee of Chinese Medical Science, and a committeeman of the 2nd and 3rd Drug Evaluation Committee of Ministry of Health. LI Guoqiao is one of compers of clinical study on artemisinin compounds in china, has engaged in clinical study of antimalarial

drugs for more than 40, and has abundant experience and ability to solve actual problem.

Li Guoqiao took part in the development of new antimalarial drugs "523 Project" which was disposed by Premier Zhou in 1967 and confirmed that artemisinin compounds have effect of rapidly and effectively treat falciparum malaria and show low toxicity in 1974 for the first time, and a high healing rate was obtained by prolonging clinical curative course. He discovered that artemisinin compounds can inhibit and kill gametophytes of Plasmodium falciparum for the first time, which produces positive effect of demonstrating that artemisinin compounds can hold back and prevent the spreadability of falciparum malaria, and stated a new opinion that Plasmodium falciparum are not easy to produce drug resistance to artemisinin compounds for the first time. He possesses two granted invention patent applications relating to compound artemisinin antimalarial drugs, i.e. ZL97114291.2 and ZL 03146951.5. The study on cerebral malaria remedy presided by Li Guoqiao arrives at the international advanced level.

Li Guoqiao discovered that fever occurs for twice during the schizogenous cycle (48 hours) of Plasmodium falciparum, which shows the reasons causing irregular fever types, proposed the theory concerning two fevers of falciparum malaria and the theory concerning two coma stages of cerebral malaria, originated a intradermal blood smear method for diagnosing two comas of cerebral malaria and the prognosis thereof. Li Guoqiao confirmed that artemisinin has effect of treating falciparum malaria for the first time, presided the clinical study on four class I new artemisinin drugs, and confirmed that artemisinin drugs are the preferred drugs useful for the treatment of severe malaria and can inhibit and kill gametophytes of falciparum malaria to thereby hold back the spreadability of falciparum malaria for the first time, and lay down a regimen with seven-days course which is approved by WHO as a standard. Li Guoqiao invented and improved 4 compound artemisinin antimalarial drugs which have the advantages such as high and rapid efficiency, short course, low toxic side effect, and low cost, thereby solving the problems such as long course, high cost and difficult popularization in poor regions when single artemisinin drug is administrated, for example, the compound CV8 has become the first-line medicine in Viet Nam, which promotes that WHO approved that compound artemisinin drugs as the first-line medicines.

Li Guoqiao published about 50 articles relating to malaria and artemisinin, wherein 3 articles are cited by the academic journals included by SCI for 213 times.

Li Guoqiao compiled "Clinical Study of Malaria", the chapter of severe malaria of

"Prevention and Research of Malaria In China", and the chapter of clinical manifestation and therapy of "Practical Malariology", wrote more than 30 articles including "Artemisinin and derivatives thereof for treating cerebral malaria. The explanations and illustrations concerning falciparum malaria fever type proposed by LI Guoqiao were included in "Malariology" edited by specialists of WHO in 1988, and the intradermal blood smear method was recited in medicinal schoolbook of Oxford University (1987 edition). In addition, the academic articles published in Journal of Medicine and Lancet are primary reference information for clinical study of artemisinin drugs.

LI Guoqiao was awarded with the certificate "Midlife and Youth Specialists Making Significant Contribution" in 1986, is one of the first specialists enjoyed government allowance granted by the State Council, and got a "Wuyi" Work Medal in 1986.

LI Guoqiao was awarded a title of model worker by the State Council in 1987.

LI Guoqiao was elected as a deputy to the National People's Congress in 1993.

LI Guoqiao was awarded a Bethune Medal by ministry of personnel, Ministry of Health and State Administration of Traditional Chinese Medicine in 2000.

LI Guoqiao was awarded a golden knight medal by Cambodia on June 21, 2006.

LI Guoqiao was awarded a medal "for the health of people" by Vietnam on March 27, 2007.

LI Guoqiao was awarded an International contribution prize of traditional Chinese medicine in April, 2008.

Resume

Name: Song Jianping

Song Jianping was born in Huichang County, JiangXi Province On March 14, 1965, and is a professor, a doctor of medicine and a supervisor of masters.

Education background

Period	College or University	Specialty	length of schooling (year)	Degree
Sep.1981-Jul.1986	Chinese medicine department, Jiangxi College of Traditional Chinese Medicine	Chinese medicine	5	bachelor
Sep. 1988-Jul.1991	Jiangxi College of Traditional Chinese Medicine	golden chamber	3	master
Sep.1998-Jul.2001	Guangzhong University of Traditional Chinese Medicine	Clinical basis of Chinese Medicine	3	doctor

Work Experience

Period	Employer
Jul.1986-Aug.1988	Traditional Chinese Medicine Hospital, Jiangxi Huichang County
Sep.1988-Aug.1998	Chinese Medicine Department, Jiangxi College of Chinese Medicine, associate professor, lecture, physician-in-charge
Sep.1998-now	Institute of Tropical Medicine, Guangzhou University of Chinese Medicine, associate professor, researcher

Academic specialties

Song Jianping has studied the prevention and treatment of tropical diseases using traditional Chinese medicines and engaged in the clinical study of artemisinin drugs and compound thereof from 1998.

(1) Research on the prophylaxis and treatment of malaria using artemisinin drugs and compound thereof. Song Jianping, being a primary researcher, took part in the pharmacodynamic and toxicologic tests of antimalarial drugs including Compound Dihydroartemisinin Tablets, Dihydroartemisinin Piperaquine tablets and Compound Complex Naphthoquine Tablets before clinical application and clinical trials thereof, wherein Dihydroartemisinin Tablets and Dihydroartemisinin Piperaquine tablets have new drug certificate and production certificate, and Compound Complex Naphthoquine Tablets get clinical approval document. In 2001 to 2002, working together with WHO, EU, Oxford University, University of Western Australia and Ministry of Health of Cambodia, Song Jianping presided and assisted the study of clinical trial of Artekin in Cambodia, Burma, Thailand, Vietnam and Indonesia, and achieved the clinical observation and valuation of 4000 uncomplicated falciparum malaria, thereby confirming the security and efficacy of Dihydroartemisinin Piperaquine tablets.

Song Jianping, being a leader, has organized the clinical study of the fourth generalization of compound artemisinin drug (Artequick) in 7 hospitals Cambodia, Thailand, Vietnam and Indonesia from July 2003, and has achieved 1000 II and III phases therapy control trials to promote the new development of Artequick.

(2) Song Jianping has took part in the implementation of artequick in Cambodia and Comorin from July 2003 Kampong.

(3) The treatment of cerebral malaria. On the basis of the experiences for treatment of cerebral malaria of Li Guoqiao, the study that artemisinin drugs are reasonably and opportunely administered to reduce mortality rate of cerebral malaria conducted by Song Jianping progressed. In 2000-2001, Song Jianping was dispatched by Ministry of Health and Guangzhoun University of Chinese Medicine as a vice-leader of Chinese specialist group for treatment of cerebral malaria to direct the treatment of cerebral malaria in Battambang Hospital of Cambodia in 2000-2001, and controlled the mortality rate of cerebral malaria to 8.3% successfully.

Selected Articles

No.	Title	Date	Name of Journal
1	A comparative study of dihydroartemisinin compounds in the treatment of uncomplicated falciparum malaria in Kampong of Cambodia	2003,9(1):31	Chinese Journal of Integrated Traditional and Western Medicine (ISSN1672-0415)

2	Controlled trial of dihydroartemisinin piperazine in treatment of uncomplicated falciparum malaria in Cambodia	2003, 83 (12), 1099-1100	Chinese Medical Journal (ISSN0376-2491)
3	Dosage Verification of Compound Naphthoquine for Falciparum Malaria	2001, 67 (1) 19-21	Journal of Guangzhou University of Traditional Chinese Medicine (ISSN1007-3213)
4	A Two-day Course of Compound Dihydroartemisinin Falciparum Malaria: A Report of 50 Cases	2000, 66(3) 238-240	Journal of Guangzhou University of Traditional Chinese Medicine (ISSN1007-3213)
5	Randomized-Control Trial of Compound Dihydroartemisinin in Treating Uncomplicated Falciparum Malaria in Hainan Province of China	2004, 21(1): 10-13	Journal of Guangzhou University of Traditional Chinese Medicine (ISSN1007-3213)
6	Randomized trial of Artekin and Artekin(T) for treatment of uncomplicated falciparum malaria patients	2003, 3 (6), 723-725	China Tropical Medicine (ISSN1009-9727, CN46-1064/RIS)
7	Randomized controlled trial of dihydroartemisinin piperazine phosphate tablet in treatment of uncomplicated falciparum malaria	2004, 23 (11) : 41-43	Chin. J. New Drugs Clin. Rem (ISSN 1007-7669 CN 31-1746/R)
8	Clinical Summary of dihydroartemisinin piperazine phosphate tablet in treatment of uncomplicated falciparum malaria		Journal of Guangzhou University of Traditional Chinese Medicine (ISSN1007-3213)
9	A Pilot Project on Fast Eliminating Malaria by Eradicating Source in A Highly Malaria Endemic Area	2006, (23) 2, 89-94	Journal of Guangzhou University of Traditional Chinese Medicine (ISSN1007-3213)
10	Novel Antimalarial Drug-Compound Dihydroartemisinin	2004, 19 (supp.), 20-23	China Journal of Traditional Chinese Medicine and Pharmacy

11	Dosage exploring of artemisinin-piperaquine In treatment of uncomplicated falciparum malaria	2008, (27) 12, 908-11	Chin. J. New Drugs and Clinic (ISSN 1007-7669 CN 31-1746/R)
12	A randomized,controlled trial of artemisinin-piperaquine vs dihydroartemisinin-piperaquine phosphate in treatment of falciparum malaria	2009 15 (3) : 189-192.	Chin J Integr Med

Teaching and Scientific Research Achievements

(1) Novel Antimalarial Drug- Compound Dihydroartemisinin, the second prize of Science and Technology Prize awarded by Guangdong Province

(2) Novel Antimalarial Drug- Compound Dihydroartemisinin, the second prize of Science and Technology Prize awarded by China Association of Chinese Medicine

(3) Development and application of compound artemisinin in the treatment of drug-resistance falciparum malaria, the second prize of State Science and Technology Development

(4) Invention Patent,ZL03146951.5

(5) Taking part in the research of artemisinin piperaquine phosphate tablet, class I new chemical drug, GuoyaoZhengzi No. H20060262 and production license number 2008B01687.

(6) Taking part in the research of piperaquine, a new drug, GuoyaoZhengzi No. H20060474 and production of license number 2008B01688.